

FORM PTO-1390 (Modified)  
(REV 11/2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371174 09/980,360  
U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR  
09/980,360INTERNATIONAL APPLICATION NO.  
PCT/US00/14875INTERNATIONAL FILING DATE  
30 May 2000PRIORITY DATE CLAIMED  
3 June 1999

## TITLE OF INVENTION

Modified Biodegradable Polyester Microspheres for Stabilizing and Improving the Release Profile  
of Drugs Encapsulated within the Microspheres

APPLICANT(S) FOR DO/EO/US

BAILEY, Leonard C. et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31):
5. ☐ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). - two
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A copy of the International Search Report (PCT/ISA/210).

## Items 13 to 20 below concern document(s) or information included:

13. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
20. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
21. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
22. ☐ Certificate of Mailing by Express Mail
23. ☒ Other items or information:

Notification of Missing Requirements

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.492(a)(1)-(5)) : <b>09/980,360</b>	INTERNATIONAL APPLICATION NO. : <b>PCT/US00/14875</b>	ATTORNEY'S DOCKET NUMBER : <b>RU-0174</b>
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24. The following fees are submitted: <b>BASIC NATIONAL FEE ( 37 CFR 1.492 (a) (1) - (5)) :</b>				<b>CALCULATIONS PTO USE ONLY</b>	
<input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... <b>\$1040.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... <b>\$890.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... <b>\$740.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... <b>\$710.00</b> <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... <b>\$100.00</b>					
<b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>				<b>\$0.00</b>	
Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				<b>\$130.00</b>	
<b>CLAIMS</b>	<b>NUMBER FILED</b>	<b>NUMBER EXTRA</b>	<b>RATE</b>		
Total claims	- 20 =	0	x \$18.00	<b>\$0.00</b>	
Independent claims	- 3 =	0	x \$84.00	<b>\$0.00</b>	
Multiple Dependent Claims (check if applicable).				<input type="checkbox"/>	<b>\$0.00</b>
<b>TOTAL OF ABOVE CALCULATIONS =</b>				<b>\$130.00</b>	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27). The fees indicated above are reduced by 1/2.				<b>\$65.00</b>	
<b>SUBTOTAL =</b>				<b>\$65.00</b>	
Processing fee of <b>\$130.00</b> for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				<b>\$0.00</b>	
<b>TOTAL NATIONAL FEE =</b>				<b>\$65.00</b>	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable).				<input checked="" type="checkbox"/>	<b>\$40.00</b>
<b>TOTAL FEES ENCLOSED =</b>				<b>\$160.00</b>	
				<b>Amount to be: refunded</b>	<b>\$</b>
				<b>charged</b>	<b>\$</b>

- a. ☐ A check in the amount of \_\_\_\_\_ to cover the above fees is enclosed.
- b. ☒ Please charge my Deposit Account No. **50-1619** in the amount of **\$160.00** to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. **50-1619**. A duplicate copy of this sheet is enclosed.
- d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

Jane Massey Licata, Reg. No. 32,257  
Kathleen A. Tyrrell, Reg. No. 38,350  
Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

Telephone: (856) 810-1515  
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*Kathleen A. Tyrrell*  
SIGNATURE  
Kathleen A. Tyrrell  
NAME  
38,350  
REGISTRATION NUMBER  
April 2, 2002  
DATE

**Response To Notice To File Missing Parts Of Application  
Filing Date Granted (PTO-1533)(Small Entity)**

Docket No.  
RU-0174

In Re Application Of: **Bailey and Shao**

Serial No.  
09/980,360

Filing Date  
November 30, 2001

Examiner  
Not Yet Assigned

Group Art Unit  
Not Yet Assigned

Invention: **Modified Biodegradable Polyester Microspheres for Stabilizing and Improving the  
Release Profile of Drugs Encapsulated within the Microspheres**

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Box Missing Parts

This is a response to the Notice to File Missing Parts of Application - Filing Date Granted (PTO-1533) mailed on  
January 30, 2002  
Date

Enclosed herewith for filing are the following:

- ☒ A copy of the Notice to File Missing Parts of Application - Filing Date Granted (PTO-1533). **(REQUIRED)**
- ☒ An oath or declaration in compliance with 37 CFR 1.63, including residence information and identifying the application by the above Application Number and Filing Date.
- ☐ A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date.
- ☐ An oath or declaration in compliance with 37 CFR 1.63 listing the names of all inventors and signed by the omitted inventor(s), identifying this application by the above Application Number and Filing Date.
- ☐ A verified English translation of the non-English language application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the United States Patent and Trademark Office.
- ☐ \_\_\_\_\_ verified small entity declaration(s)
  - ☐ is/are attached.
  - ☐ was/were filed on \_\_\_\_\_
- ☐ A separate request for refund.
- ☐ Other (list):

**Response To Notice To File Missing Parts Of Application**  
**Filing Date Granted (PTO-1533)(Small Entity)**

Docket No.  
RU-0174

In Re Application Of: **Bailey and Shao**

Serial No.  
09/980,360

Filing Date  
November 30, 2001

Examiner  
Not Yet Assigned

Group Art Unit  
Not Yet Assigned

Invention: **Modified Biodegradable Polyester Microspheres for Stabilizing and Improving the Release Profile of Drugs Encapsulated within the Microspheres**

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Attention: Manager, Application Branch

☐ Completion of application fees as calculated below:

☐ Utility application filing fee

☐ Design application filing fee

☐ Total number of independent claims = \_\_\_\_\_

☐ Total number of claims = \_\_\_\_\_

☐ Multiple dependent claims

☒ Surcharge for late payment of filing fee and/or late filing of original declaration or oath **\$65.00**

☐ Petition and fee for filing by other than all the inventors or a person not the inventor

☐ Fee for processing an application filed with a non-English language specification

☐ Fee for processing and retention of application

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Total completion of application fees

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a response to the above-identified Notice to File Missing Parts of Application. The requested extension is as follows (check time period desired). If an additional time extension is required, please consider this a petition therefor.

☒ One month ☐ Two months ☐ Three months ☐ Four months ☐ Five months

from: March 31, 2002 until: April 30, 2002  
Date Date

Total time extension fees **\$55.00**

Total fees due **\$120.00**

**Response To Notice To Missing Parts Of Application**  
**Filing Date Granted (PTO-1533) (Small Entity)**

Docket No.  
RU-0174

In Re Application Of: **Bailey and Shao**

Serial No.  
09/980,360

Filing Date  
November 30, 2001

Examiner  
Not Yet Assigned

Group Art Unit  
Not Yet Assigned

Invention: **Modified Biodegradable Polyester Microspheres for Stabilizing and Improving the Release Profile of Drugs Encapsulated within the Microspheres**

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

Attention: Manager, Application Branch

The fee of **\$120.00** is to be paid as follows:

- ☐ A check in the amount of the fee is enclosed.
- ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. **50-1619**  
A duplicate copy of this sheet is enclosed.
- ☒ If an additional extension of time is required, please consider this a petition therefor and charge any additional fees which may be required to Deposit Account No. **50-1619**  
A duplicate copy of this sheet is enclosed.

*Kathleen A. Tyrrell*  
Signature

Dated: **April 2, 2002**

Jane Massey Licata, Reg. No. 32,257  
Kathleen A. Tyrrell, Reg. No. 38,350  
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I hereby certify that this document being deposited on **April 2, 2002** with the United States Postal Service as First Class Mail under 37 C.F.R. 1.8 and is addressed to the U.S. Patent and Trademark Office P.O. Box 2327, Arlington, VA 22202.

By

*Kathleen A. Tyrrell*  
Typed Name: Kathleen A. Tyrrell

cc: